

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE) MDL No. 1456
LITIGATION)
)
) Judge Patti B. Saris
)
THIS DOCUMENT RELATES TO)
01-CV-12257-PBS and 01-CV-339)
)
)
TRIAL OF CLASS 2 AND 3 CLAIMS

**DEFENDANT ASTRAZENECA PHARMACEUTICALS LP'S
MEMORANDUM OF LAW IN RESPONSE TO
PLAINTIFFS' AUGUST 1, 2007 DAMAGES SUBMISSIONS**

AstraZeneca Pharmaceuticals LP ("AstraZeneca") respectfully submits this memorandum of law in response to Plaintiffs' Memorandum in Support of an Award of Treble Damages in Connection with the Class 2/3 Trial [Docket Entry No. 4533] ("Pl. Treble Mem.") and Plaintiffs' Memorandum in Support of Track 1 Damages Submission [Docket Entry No. 4535] ("Pl. Damages Mem."). For the reasons articulated below, AstraZeneca contends that treble damages are not appropriate and reiterates its objections to Plaintiffs' calculation of aggregate damages.

ARGUMENT

For the first time, on August 1, Plaintiffs revealed their "final" damages calculations, which include trebling and revised interest calculations for Classes 2 and 3. (*See generally* Pl. Damages Mem.; Pl. Treble Mem.) To the extent that Plaintiffs suggest that AstraZeneca does not dispute these figures or the manner in which they were calculated (Pl. Damages Mem. at 3), Plaintiffs are wrong.

I. Treble Damages Are Not Appropriate

As a threshold matter, the Court’s June 21, 2007 Findings and Conclusions determined Class 3 damages and only left open the mathematical calculation of Class 2 damages based upon “a breakdown of the damages for each drug, using the 30% threshold, for each of the years from 1998 until 2003” for which liability was found. *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12557, MDL No. 1456, 2007 WL 1774644, at *73 (June 21, 2007). Plaintiffs may not now use this request for specific data points as an opportunity to effectively seek reconsideration of the Court’s Findings and Conclusions, which, despite Plaintiffs’ request for multiple damages at trial, did not award such damages.

Regardless, Plaintiffs are not entitled to recover treble damages under section 9 of Chapter 93A. Multiple damages, which are considered a “severe sanction” and an “extraordinary penalty,” do not automatically flow from a finding of liability under Chapter 93A. *VMark Software, Inc. v. EMC Corp.*, 642 N.E.2d 587, 596 (Mass. App. Ct. 1994) (finding liability under Ch. 93A for intentional misrepresentation, but declining to award double damages); *see also, e.g., Damon v. Sun Co.*, 87 F.3d 1467, 1483 (1st Cir. 1996) (affirming district court’s dual finding of liability based on intentional misrepresentation and denial of multiple damages); *Int’l Totalizing Sys., Inc. v. PepsiCo, Inc.*, 560 N.E.2d 749, 757 (Mass. App. Ct. 1990) (finding liability for knowing misrepresentation for failure to disclose, but no liability for multiple damages). To the contrary, as the First Circuit has observed, “shades of culpability are supposed to matter in applying the punitive damages provision of the statute” and as such, “liability under Chapter 93A for conduct amounting to intentional misrepresentation does not trigger

punitive damages. There must be something more.” *Cambridge Plating Co. v. Napco, Inc.*, 85 F.3d 752, 770 (1st Cir. 1996).

Multiple damages are only appropriate for “truly inequitable marketplace behavior, which unmistakably reeks of callousness, bad faith, and of meretriciousness,” *VMark Software, Inc.*, 642 N.E.2d at 624 (citations omitted), such as when a defendant “act[s] maliciously” towards the plaintiff or “remains silent in order to watch the plaintiff suffer,” *Kimiatek v. Mendelson*, No. 045129, 2007 WL 738700, at *4 (Mass. Super. Ct. Jan. 22, 2007). Indeed, there may even be evidence of “bad faith and willful intent to deceive” on the defendant’s part, but there must be some “quantum of knowing or willful violation,” sufficient to justify the imposition of punitive damages. That is, the defendant’s actions must be “knowing and willful *enough*” to merit this penalty. *Damon*, 87 F.3d at 1485 (emphasis added).

For instance, in *Cambridge Plating Co.*, the First Circuit reversed an award of multiple damages under Chapter 93A premised on the trial court’s finding that the defendant failed to disclose a fact that it knew to be material, which resulted in harm to the plaintiff. 85 F.3d at 770. Noting that the district court imposed “double damages based on essentially the same finding upon which it imposed substantive liability,” the court stated that “[a]t first blush, this conclusion may seem sound, given the ‘willful or knowing’ language of the statute. [Defendant’s] conduct, which also amounts to intentional misrepresentation . . . clearly involves a certain level of deliberateness.” *Id.* Nonetheless, the Court of Appeals concluded that if the defendant’s conduct was “fraud”

and a “willful repudiation of warranty,” based on the record, it was “only marginally so,” and therefore could not support a finding of double damages. *Id.*¹

Although there has been a finding of liability as to Classes 2 and 3 under Chapter 93A, AstraZeneca respectfully submits the context and conduct here do not support the imposition of multiple damages. As the Court found, “[w]hat Congress understood and intended AWP to mean is not the same as what the industry understood.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1774644, at *61. The Court’s findings, and the supporting evidence in the record, demonstrate that AstraZeneca acted in good faith with the belief not only that AWP was never intended to be an actual average price, but also that information was available to the government and third-party payors about the specific discounted prices paid by physicians for Zoladex.

In considering this issue, the context in which AstraZeneca’s conduct occurred is important. As the Court’s findings demonstrate, there was substantial public discussion during the relevant time period among government agencies about the fact that AWP was not an accurate predictor of acquisition prices. *Id.* at *12-14. That discussion was followed by repeated attempts to amend the reimbursement system for Medicare Part B-covered products to better approximate acquisition costs and on a number of occasions

¹ Plaintiffs’ citation to “fact patterns justifying awards of multiple damages under Section 9” (Pl. Treble Mem. at 3-4) involving transactions with individual consumers is irrelevant. AstraZeneca has already agreed to effectively pay more than double damages to the members of Class 1 who submit valid claims in connection with a settlement of those claims. (See Class 1 Settlement Agreement and Release of AstraZeneca by All Plaintiffs (May 21, 2007) [Docket Entry No. 4227].) Here, Plaintiffs are seeking damages for members of Classes 2 and 3, which are *institutional entities*, not individuals. The Court’s findings demonstrate that these institutional entities are differently situated than individuals. These institutions not only had greater access to information, but also failed to eliminate AWP as the basis for reimbursement even after it was clear that AWPs exceeded acquisition costs. As the Court noted: “Remarkably, BCBSMA, the behemoth insurer in the Massachusetts market, and other large TPPs, were not proactive in adjusting to cost data once Medicare did the legwork for them in devising more reasonable drug pricing and service fees.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1774644, at *16. Such behavior from sophisticated entities, is easily contrasted with that of individuals.

until 2003, those efforts were rejected. *Id.* As the Court observed, as a result of this AWP-based system, AstraZeneca “faced a difficult competitive situation,” *id.* at *22, because it “created a financial incentive for physicians to choose higher priced products for their Medicare patients,” *id.* at 21; *see also* Defendant AstraZeneca Pharmaceutical LP’s Proposed Findings of Fact (“AZ FF”) ¶ 20 (Jan. 19, 2007) [Docket Entry No. 3569].

The Court’s findings also acknowledge that AstraZeneca sent CMS its average manufacturer prices for Zoladex on a quarterly basis since 1991. *See id.* at *67. That AMP data were a “close proxy” for the Zoladex ASP, *id.*, further demonstrates that AstraZeneca did not engage in the type of knowing and willful deceit necessary to support an award of multiple damages. There is no evidence that AstraZeneca somehow tricked the government into basing reimbursement for Zoladex on AWP. Indeed, at one point, a Medicare carrier attempted to base reimbursement for Zoladex on the physician’s acquisition cost when it obtained a copy of the Zoladex volume discount schedule. The carrier even sent a copy of that schedule to HCFA. Rather than change the reimbursement rate for Zoladex, HCFA directed him to cease reimbursement based on acquisition cost, and further “not to collect invoices from physicians in order implement an acquisition cost survey.” *Id.* at *5 (citing Trial Affidavit of Gregory K. Bell, Ph.D. ¶ 84 (Nov. 26, 2006) [Docket Entry No. 3416]); *see also* AZ FF ¶¶ 61-63; *id.* ¶¶ 64-65 (reporting a similar incident, this time with regard to the Medicare Carrier for South Carolina).

Additionally, as the Court also acknowledged, “[t]o its credit, outside of the Medicare system, AstraZeneca attempted to compete with TAP by setting up reimbursement programs that didn’t rely on AWP.” *In re Pharm. Indus. Average*

Wholesale Price Litig., 2007 WL 1774644, at *24. AstraZeneca did this by first “encourag[ing] health care plans to adopt a maximum allowable cost on Zoladex and Lupron equal to Zoladex’s WAC price.” *Id.*; *see also* AZ FF ¶¶ 38-40, 51. Second, AstraZeneca launched a “‘Bill to/Ship to’ program, which was later renamed the Managed Acquisition Program” pursuant to which managed care organizations could purchase Zoladex directly from AstraZeneca at discounted prices and AstraZeneca would ship Zoladex directly to the physician, thereby removing the physician from the financial transaction altogether, “allowing the health plans to benefit from the discounted prices.”

In re Pharm. Indus. Average Wholesale Price Litig., 2007 WL 1774644, at *24; *see also* AZ FF ¶¶ 38-50. In the course of these discussions, AstraZeneca affirmatively informed third-party payors of the discounted prices being paid by physicians, as well as the comparisons being made to the competing product. Some of these TPPs, most significantly BCBS MA, were not only members of Class 3, but also members of Class 2 as well.

Further, the Court found that there was other information available to TPPs about Zoladex discounts. AstraZeneca itself provided Staff Model HMOs affiliated with certain TPPs prices similar to Dr. Hartman’s ASPs. *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1774644, at *17-19; *see also* AZ FF ¶¶ 36-37. Moreover, as the Court found, publicly available IMS Health data on Zoladex sales to physicians closely tracked the “average sales prices” calculated by Plaintiffs’ expert, Dr. Hartman, for 1999-2003, the years where the Court found liability as to AstraZeneca. *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1774644, at n.66; *see also* AZ FF ¶ 68.

Finally, AstraZeneca believed that its discount practices financially benefited patients, the system, and Class members. Because the price of Zoladex (as well as the average price increase) was always lower than that of Lupron, “patients, the Medicare program, and private insurers paid less when Zoladex was administered instead of Lupron.” *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1774644, at *21. When the least costly alternative policy was introduced, Medicare Part B carriers used the Zoladex AWP (as reported by independent, third-party publishers, *id.* at *3; *see also* AZ FF ¶ 13) as a basis for reimbursement for both Lupron and Zoladex, resulting in further savings for the system. *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1774644, at *21. Contrary to Plaintiffs’ suggestion that AstraZeneca was “callous with respect to the consequences of its misrepresentations and manipulations” (Pl. Treble Mem. at 9), AstraZeneca believed that leveling of the playing field between Zoladex and Lupron resulted in lower costs to patients and the healthcare system by creating an incentive for physicians to use the lower priced drug, Zoladex. *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1774644, at *22; *see also* AZ FF ¶¶ 25, 31-33.²

In sum, the Court’s findings do not support a conclusion that AstraZeneca acted with malice or with the level of callousness necessary to justify the extraordinary remedy of treble damages. To the contrary, the Court’s findings show that AstraZeneca’s conduct occurred in the context of a reimbursement system that disadvantaged Zoladex by creating incentives for higher priced products, but that nonetheless, AstraZeneca kept

² As one AstraZeneca witness testified, he felt “good” about the fact that Zoladex imposed a lower overall cost on the healthcare system and the patient. *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1774644, at *21. Plaintiffs’ suggestion that this is evidence of callousness (*see* Pl. Treble Mem. at 9) is absurd. It is hardly malicious to feel “good” about saving consumers and the system money.

its product the lower cost alternative, provided information to TPPs and the government about its discounting activities, and even tried to advocate with TPPs for a different reimbursement model altogether. Under these circumstances, the imposition of multiple damages is not warranted, and would run counter to well established principles of Massachusetts law.

II. Dr. Hartman's Methodology is Flawed

Moreover, with respect to the calculation of single aggregate damages for Class 2, AstraZeneca reiterates its objections to Dr. Hartman's methodology. Plaintiffs' request for an aggregate damages award for Class 2 completely sidesteps the separate damages determination process Plaintiffs proposed in response to Defendants' arguments that individual damages issues predominated. (*See, e.g.*, Plaintiffs' Memorandum in Support of Class Certification, App. C (Sept. 3, 2004).) Indeed, Dr. Hartman's calculation of Class 2 damages is not based in any way on evidence of actual damages sustained by any member of Class 2; it is not even based on basic information regarding the members of Class 2 or the number of beneficiaries insured by Class 2 members.³ Instead, to calculate class-wide damages Dr. Hartman inappropriately relies on *AstraZeneca's* transactional sales data—a data set that includes no information on whether the units were ultimately reimbursed by a third-party payor, and if so, how the reimbursement was calculated. Indeed, this approach simply *assumes* liability as to every unit sold in years when the spread between the “average sale price” and the AWP for Zoladex exceeded Dr. Hartman's self-created 30% “expectation” yardstick, which is itself an unsupported

³ Dr. Hartman used the same flawed methodology in connection with his calculation of aggregate damages for Class 3. (*See, e.g.*, Affidavit of Eric M. Gaier, Ph.D. Submitted as Direct Testimony in Case-In-Chief of Track 1 Defendants in the Trial of Class 2 and Class 3 Claims ¶¶ 56-59.)

assumption contrary to basic economic theory, the economics of the pharmaceutical industry, the facts of this case, and the scientific method generally.⁴

Dr. Hartman then compounds the error by applying a series of additional mathematical “assumptions” in order to approximate the proportion of the units sold by AstraZeneca that might have been reimbursed through Medicare Part B and might have had the co-payment paid in whole or in part by a third-party payor. Typical of these assumptions is the last one to be disclosed: after submitting reports over the past three years in connection with class certification, summary judgment, liability, and the Trial of Class 2 and Class 3,⁵ Dr. Hartman now—for the first time—incorporates an assumption that six in 10 (60%) of employer-sponsored supplemental insurance plans require beneficiaries to pay a 20% coinsurance, citing an article entitled, “Large Firms’ Retiree Health Benefits Before Medicare Reform: 2003 Survey Results,” by Frank B. McArdle et al., *Health Affairs*, at W4-7 (Jan. 14, 2004). Even setting aside the fact that late disclosure of this new calculation is highly prejudicial to AstraZeneca, a stray statement

⁴ (*See generally*, e.g., Track 1 Defendants’ Renewed Motion to Strike the Expert Testimony of Dr. Raymond Hartman in Connection with the Trial of Class 2 and Class 3 (Jan. 19, 2007) [Docket Entry No. 3575]; Track 1 Defendants’ Memorandum in Support of Their Motion to Preclude the Expert Testimony of Dr. Raymond Hartman in Connection with Classes 1 and 2 (June 16, 2002) [Docket Entry No. 2723]; Affidavit of Eric M. Gaier, Ph.D. Submitted as Direct Testimony in Case-In-Chief of Track 1 Defendants in the Trial of Class 2 and Class 3 Claims [Docket Entry No. 3343].)

⁵ (*See, e.g.*, Declaration of Raymond S. Hartman in Support of Plaintiffs’ Motion for Class Certification (Sept. 3, 2004); Rebuttal Declaration of Raymond S. Hartman in Response to the Sur-Reply Declaration of Steven J. Young (Mar. 9, 2005), *stricken* by Docket Entry No. 1456; Declaration of Raymond S. Hartman in Support of Plaintiffs’ Claims of Liability and Calculation of Damages (Dec. 15, 2005); Supplemental Declaration of Raymond S. Hartman in Support of Plaintiffs’ Claims of Liability and Calculation of Damages: Addendum (Feb. 3, 2006); Reply Declaration of Raymond S. Hartman in Support of Plaintiffs’ Motion for Summary Judgment (July 14, 2006); Affidavit of Direct Testimony of Raymond S. Hartman (Nov. 1, 2006) [Docket Entry No. 3296]; Affidavit of Rebuttal Testimony of Dr. Raymond Hartman (Dec. 15, 2006) [Docket Entry No. 3470]; Report of Raymond S. Hartman Regarding AstraZeneca with Respect to Class 1 (Mar. 16, 2007) [Docket Entry No. 3857].)

made in single article hardly provides strong empirical support for Dr. Hartman's methodology.

For the foregoing reasons, as well as all other objections articulated in prior filings, AstraZeneca respectfully reiterates its objections to Dr. Hartman's calculation of aggregate damages for Class 2.

CONCLUSION

For the foregoing reasons, AstraZeneca respectfully requests that this Court deny Plaintiffs' demand for treble damages.

Dated: Boston, Massachusetts
August 6, 2007

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered on August 6, 2007 to counsel for plaintiffs and to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, via LexisNexis File & Serve.

By: /s/ Katherine B. Schmeckpeper
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